# SUMMARY REPORT

Canada - U.S. Bilateral Discussions on Agricultural Biotechnology
July 15-16, 1998
Ottawa, Ontario, CANADA

## PURPOSE OF THE MEETING

Regulatory officials of Canada and the United States met to compare, and harmonize where possible, aspects of molecular genetic characterization that are part of their review processes for transgenic plants. Agreement on common requirements and acceptable analytical approaches for molecular genetic characterization will facilitate the submission of these characterization data by developers seeking regulatory approval to incorporate such plants into agricultural production or commerce in both countries.

## BACKGROUND

In a continuation of U.S. and Canadian efforts to harmonize the review process for transgenic plants prior to commercialization, this meeting provided an opportunity to build upon the exchange of information that has occurred at previous bilateral discussions and in concurrent reviews of transgenic plants prior to commercialization. The participating agencies were the Canadian Food Inspection Agency (CFIA), Health Canada, and the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS).

The framework for the regulation of transgenic plants in Canada and the U.S. is comparable, but there are some subtle differences. In Canada, the CFIA is responsible for the regulation of importation, environmental release and feed use of plants with novel traits which includes, but is not limited to, transgenic plants. Health Canada has jurisdiction over novel foods, including food products derived from transgenic plants. In the U.S., APHIS is responsible for the regulation of importation, interstate movement, and environmental release of transgenic plants that contain plant pest components. Regulatory authority for food and feed use in the United States lies with the Food and Drug Administration (FDA). The U.S. Environmental Protection Agency (EPA) registers certain pesticides produced in transgenic plants prior to their distribution and sale and establishes tolerances for the pesticides in the plants.

## OBJECTIVES OF THE MEETING

1. Identify molecular genetic characterization data relevant to the review of transgenic plants by the participating agencies.
2. Identify common techniques or analytical approaches used for molecular genetic characterization.
3. Discuss exchange of information related to technical reviews and other areas of cooperation.

**OUTCOMES**

1. Participants agreed on commonalities in the molecular genetic characterization data (see Appendix I: Molecular Genetic Characterization Data).

2. Participants agreed to develop reviewers' checklists which will be used in the assessment process for the following six analytical techniques :
   - Southern blots
   - Western blots
   - Northern blots
   - Polymerase chain reactions (PCR)
   - Dot blots
   - Enzyme-linked immunosorbent assay (ELISA)

   These checklists should be completed by October 1, 1998.

3. Participants agreed to exchange information on:
   - biochemical and metabolic characterization data;
   - commonalities in the assessment criteria and data used for evaluating environmental safety of transgenic plants; and
   - processes for streamlining the importation of transgenic plant commodities for processing or consumption.

   Information exchange will be conducted via:
   - quarterly telephone conference calls beginning October 27, 1998;
   - joint reviews of applications/petitions submitted to both the U.S. and Canada;
   - meetings as needed (at least annually; next meeting scheduled for June 1999); and
   - publication of meeting results, reviewers' checklists, etc. on the agencies' respective web sites.

# PARTICIPANTS

**CANADIAN FOOD INSPECTION AGENCY**
**Grant Watson**, Associate Director, Variety Section, Plant Products Directorate
**Stacy Charlton**, Plant Biotechnology Office, Variety Section
**Morven McLean**, Plant Biotechnology Office, Variety Section
**Louise Duke**, Chief, Variety Registration Office, Variety Section
**Mireille Prud'homme**, Plant Health Risk Assessment Unit, Science Division, Policy Planning and Coordination Directorate
**Phil Macdonald**, Biotechnology Officer, Feed Section
**Deborah Bryanton,** International Affairs
**Diana Rowat,** Plant Biotechnology Office, Variety Section

**HEALTH CANADA**
**Paul Mayers**, Acting Director, Bureau of Microbial Hazards
**Karen McIntyre**, Acting Head, Office of Food Biotechnology
**Brian Harrison,** Scientific Evaluator, Office of Food Biotechnology

**USDA, ANIMAL AND PLANT HEALTH INSPECTION SERVICE**
**Rebecca Bech**, Assistant Director, Scientific Services, Plant Protection and Quarantine
**Susan Koehler**, Biotechnologist, Scientific Services
**David Heron**, Biotechnologist, Scientific Services